UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	

SPECIAL MASTER ORDER NO. 87

Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare U.S., LLC (collectively, the "ZHP Defendants") have moved pursuant to D. N.J. L. Civ. R. 5.3(c) to submit a redacted version of the report of Defense Expert Fengtian Xue, Ph.D., which has been filed under seal on the Court's docket in connection with Plaintiffs' *Daubert* Motion to preclude Dr. Xue's opinions. *See* ECF No. 2288-3. The ZHP Defendants have complied with the procedural requirements of Local Rule 5.3 by providing an index of the proposed redactions along with a proposed Order containing suggested findings of fact and conclusions of law. (ECF No. 2459-7.) The ZHP Defendants have also submitted the Declaration of Jucai Ge, a long-time employee of ZHP and now Executive Vice General Manager of Hubei Saiao Biopharmaceutical Co., Ltd., a subsidiary of ZHP. (ECF No. 2459-5 at ¶ 1.)

Plaintiffs oppose the request of the ZHP Defendants, contesting both the competence of Ms. Ge to provide support for the motion to redact and the bases for redacting a document that is now part of the Court record. For the reasons that follow, the ZHP Defendants' motion will be granted.

I. BACKGROUND

ZHP is a producer of the active pharmaceutical ingredient ("API") in Valsartan, an angiotensin receptor blocker ("ARB") prescribed for the treatment of hypertension (high blood pressure). Plaintiffs contend that ZHP's production processes for its Valsartan API resulted in the formation of N-nitrosodimethylamine ("NDMA") and/or N-nitrosodiethylamine ("NDEA"), suspected carcinogens. Due to this alleged contamination, Valsartan containing ZHP's API was recalled and ZHP was banned from importing its Valsartan API into the United States. This multi-district litigation ensued.

To prove their claims, Plaintiffs have produced reports from several expert witnesses. The ZHP Defendants have responded with reports from nine experts. One of those reports is a 58-page report of Dr. Xue, an expert in the field of organic and medicinal chemistry. Dr. Xue opines as follows:

> • ZHP performed reasonable and appropriate scientific risk assessments regarding the relevant manufacturing processes it used to create its Valsartan API given the information reasonably available in the field of organic chemistry at the time;

> • ZHP performed reasonable and appropriate scientific testing of its Valsartan API for potential impurities during the time that its Valsartan API was available on the market; and
> • ZHP did not know, and could not have been reasonably expected to know, that the manufacturing processes for its Valsartan API could result in the formation of NDMA or NDEA until it was alerted to the presence of these impurities in its Valsartan API by customer Novartis in 2018.

(ECF No. 2459-3 at 3.)

The ZHP Defendants have proposed modest redactions to Dr. Xue's report, none of which cover Dr. Xue's opinions on liability. The redactions appear on 13 of the 58 pages of Dr. Xue's report. For example, the ZHP Defendants seek to redact the specific temperatures mentioned in this sentence on page 16 of the Report: "The reaction was then cooled to ___ ºC, and was added to another solvent, MTBE, followed by water." The redactions in the next sentence similarly remove only two specific temperatures. Specific temperatures are also redacted on pages 28, 40, and 41 of the report. The ZHP Defendants seek to redact parts of the following Tables: Table 1a-2, titled "Main Materials Charging and Production Capacity Comparison," appearing on page 23 of the Report; Table 1a-3, "Descriptions of Main Manufacturing Process Changes," appearing on pages 26 and 27 of the Report; Table 1a-4, "Change on Critical Process Parameters," found on page 28 of the Report; Table 1a-5, "Comparison on Specification of Condensation Compound Hydrochloride (Intermediate 2)," and Table 1a-6, "Comparison on Specification of Crude Valsartan (Intermediate 4)," both of which

appear on page 29 of the Report; Table 5-1, "Optimization Experiments Result for Tetrazole Formation," found on page 32 of the Report; Table 5-2, "Experiments Result for Drag Effect to Tetrazole Formation," and Table 5-3, "Experiments Result for Toluene Effect to Tetrazole Formation," found on page 33 of the Report; and Table 1a-9, "Impurity Evaluation of Condensation Compound Hydrochloride," appearing on pages 34 through 36 of the Report.

Ms. Ge asserts that "[t]he Redacted Information includes highly sensitive and detailed information regarding ZHP's manufacturing of Valsartan" API, "including information regarding ZHP's ***current manufacturing processes*** for Valsartan API." (ECF No. 2459-5 at 3; italics and bold face in original.) Ms. Ge elaborates:

> [I]n Table 1a-2 at page 23 of Dr. Xue's Report, Dr. Xue delineates how the company changed a number of specific steps in its manufacturing process and why. Dr. Xue describes in the esterification step, after changes were made, a different amount of a particular material was used and why the quantity was changed. Dr. Xue describes a similar change in the acylation step. Disclosure of the Redacted Information in this table would reveal confidential manufacturing information that could be exploited by ZHP's competitors.
> Likewise, in Table 1a-3 on pages 26 and 27 of Dr. Xue's Report, Dr. Xue documents other manufacturing process changes with respect to particular steps, describing the step and the original process as well as the new proposed process and notes on the changes. The Redacted Information in this table (which encompasses only the data in "Proposed Process" and "Note on Changes" columns, not information relating to the original process) would provide competitors with a window not only into ZHP's current process but also its rationales for process changes, which

> could easily be exploited by other companies engaged in API manufacturing to improve their own processes at the expense of ZHP.

(ECF No. 2459-5 at 3-4.)

Plaintiffs respond by asserting that Ms. Ge is not competent to opine on the confidential nature of the redacted information and the harm to the ZHP Defendants if the information is disclosed because she is not presently working for ZHP. Plaintiffs also contend that the ZHP Defendants have failed to support their claims of competitive harm with sufficiently detailed evidence.

II. DISCUSSION

Because Dr. Xue's Report was submitted as an exhibit to Plaintiffs' *Daubert* motion and is thus part of the Court record, "[t]he scale is tipped at the outset in favor of access" to an unredacted Report. *In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 484 F. Supp. 3d 249, 262 (E.D. Pa. 2020). This presumption of public access to the Report is needed "to 'promote public confidence in the judicial system; diminish possibilities for injustice, incompetence, perjury, and fraud; and provide the public with a more complete understanding of the judicial system and a better perception of fairness." *Id.* The burden is on the ZHP Defendants to establish "good cause" for each of the proposed redactions. To carry this burden, the ZHP Defendants must show a

"clearly defined and serious injury" resulting from disclosure of the redacted material. *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994).

Plaintiffs contend that the person upon whom the ZHP Defendants rely to make this showing, Ms. Ge, is not competent to supply the necessary proof because she does not presently work for any ZHP Defendant and does not work in the Zhejiang Province where ZHP is located. It is undisputed, however, that Ms. Ge worked for ZHP for more than twenty years and has served as its corporate designee for deposition purposes in this litigation. Her employment with ZHP included serving as the Director of ZHP's Quality Assurance Department when the processes at issue in this litigation were in place. She has attested under penalties of perjury that she is personally familiar with the technical information that the ZHP Defendants seek to redact and the competitive harm that is threatened by the disclosure of the information. The fact that she now works for a subsidiary of ZHP does not disqualify her from providing reliable information concerning the need for the targeted redactions and the competitive harm posed by release of the redacted information.

Emphasizing that there is heightened interest in full disclosure of "information important to public health and safety," and that this litigation "involve issues important to the public," (ECF No. 2843 at 4), Plaintiffs also contend that the Ge Declaration does not provide the specific information to overcome the presumption

of public access to the unredacted report. Plaintiffs argue that "ZHP's motion is built entirely on broad allegations of harm," and that there is "insufficient information . . . for the Court to make the findings necessary to find in ZHP's favor. . . ." (ECF No. 2483 at 5-6.)

Plaintiffs' argument ignores the targeted nature of the limited redactions at issue here. The ZHP Defendants seek to redact only technical data and information. Courts have "protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, drug master files, formulations, and other confidential testing by drug manufacturers." *Valeant Pharm. Luxembourg S.a r.l. v. Actavis Laboratories UT, Inc.*, No. CV1604344JLLJAD, 2018 WL 1832914, at *4 (D.N.J. Apr. 16, 2018); *see also Amgen Inc. v. Zydus Pharm. (USA) Inc.,* No. CV1918806MASDEA, 2021 WL 2550449, at *2 (D.N.J. May 18, 2021); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm., Inc.*, No. CIV. 14-4727 NLH/KMW, 2015 WL 4715307, at *2 (D.N.J. Aug. 7, 2015) (sealing various parts of briefs and exhibits that contain "highly proprietary business information regarding the development, formulation, manufacture and sales of [a party's] ANDA products"); *Depomed, Inc. v. Purdue Pharma L.P.*, No. CV 13-571-MLC-TJB, 2017 WL 27460, at *1 (D.N.J. Jan. 3, 2017) (sealing documents "relating to Plaintiff's research and development efforts including . . . information

in its laboratory notebooks related to research and development efforts of its products"). Plaintiffs have not refuted the ZHP Defendants' showing that this information is confidential, highly proprietary, and valuable from a competitive perspective.

Nor have Plaintiffs demonstrated that the redacted information is essential to understanding Dr. Xue's Report or the defenses in this matter. Plaintiffs assert that Dr. Xue's Report "is one of the most important documents for someone to review before" a class member decides whether to be bound by the outcome of class action trials. (ECF No. 2483 at 10.) But the redacted technical information and data do not appear to be essential to understanding Dr. Xue's conclusions and opinions, and Plaintiffs have not even attempted to explain why that is so. Redacting the Xue Report as requested by the ZHP Defendants will not undermine public confidence in the judicial system or increase possibilities for injustice, perjury, and fraud. Nor will it create a perception of unfairness.

Plaintiffs argue that the ZHP Defendants' competitive concerns are nonetheless protected by "its numerous patents, which elaborate [ZHP's manufacturing] processes in great detail in order to establish their exclusive rights to use those processes." (ECF No. 2483 at 13.) The ZHP Defendants respond by asserting that the patents "do not include the same level of technical detail regarding ZHP's manufacturing processes and testing protocols as the portions of the Xue Report

proposed for redaction." (ECF No. 2495 at 4.) For example, the patents at issue provide *ranges of* temperatures and *ranges of* the durations for certain processes, but "the Xue Report provides specific temperature and duration of ZHP's tetrazole-formation step." (*Id.* at 5.)

The public would gain little from knowing the technical specifics of the manufacturing process, but competitors may find this information highly valuable. Furthermore, the proposed redactions are narrowly tailored. Under these circumstances, the ZHP Defendants have demonstrated both "a substantial and compelling interest in confidentiality [and] that divulgence would work a clearly defined and serious injury. . . ." *Supernus Pharm., Inc. v. TWi Pharm., Inc.*, No. 1:15-CV-00369-RMB-JS, 2019 WL 13043557, at *2 (D.N.J. June 17, 2019). Accordingly, there is good cause for granting the ZHP Defendants' request for limited redactions of the Xue Report, particularly given the fact that the bulk of the Xue Report will be on the public docket.

III. CONCLUSION

Consistent with the foregoing, the following findings of fact are made:

1. Plaintiffs filed the Xue Report in camera in connection with their motion to exclude the opinions of Dr. Xue. (*See* ECF No. 2288).

2. The Xue Report contains confidential, proprietary, and highly technical information about the manufacturing processes and testing practices and results utilized by ZHP.
3. The Xue Report is itself marked "Confidential" and contains or references information marked "Confidential" or "Restricted Confidential " under the Amended Confidentiality and Protective Order entered in this case (ECF No. 1661) (the "Confidentiality Order").
4. ZHP has treated the information in the Xue Report as confidential, including by requiring Dr. Xue to sign and agree to abide by the Confidentiality Order; the information is not a matter of public knowledge; and disclosure of such highly confidential information would cause substantial commercial harm to ZHP, including by allowing ZHP's competitors to improve their own processes at ZHP's expense.
5. The ZHP Defendants have a legitimate interest in protecting this information from disclosure and would suffer a clearly defined injury if the information were to be made public.
6. There is no less restrictive alternative available than to redact the information. The ZHP Defendants have sought to redact only that information that is entitled to protection.

7. There exists no countervailing public interest in having access to the information at issue sufficient to override the ZHP Defendants' legitimate interests in protecting against its public disclosure.
8. The ZHP Defendants have shown that they have complied with the requirements of Local Civil Rule 5.3(c)

ACCORDINGLY, IT IS HEREBY ORDERED THAT the ZHP Defendants' Motion to redact parts of Dr. Xue's Report (ECF No. 2459) is **GRANTED.**

IT IS FURTHER ORDERED THAT the ZHP Defendants will file on the Court's docket a redacted version of the Xue Report consistent with the foregoing discussion to replace the slip sheet currently filed as ECF No. 2288-3.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master